

Device and Procedure for Handheld Ophthalmic Surgery with Ultrashort Pulse Laser Radiation (Fs-Laser Handpiece for Ophthalmic Surgery)

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Abstract

The invention is related to a device and a procedure which enables to treat certain eye diseases in human eyes with help of a surgical handpiece, which delivers an ultrashort pulse laser beam for surgery. The handheld device is capable of delivering ultrashort pulsed laser energy in the femtosecond and picosecond range directly to the ocular tissue like retina, cataract and sclera.

Keywords: *Ultrashort Pulse Laser; Retina; Cataract*

Background

State of the art in ophthalmic laser surgery

Eye surgery is mainly done with help of surgical microscopes for best visualization and a certain mechanical electromechanical or also laser fiber instrument. Endoscopic laser coagulation is well known and performed during retinal surgery.

Cataract surgery is the most performed ocular surgery [1] involving removal of opaque or near opaque natural crystalline lens and replacing it with an artificial intraocular lens. About 20 million procedures are performed world-wide each year. The well-established cataract surgery which mostly is done by phacoemulsification [2] of the old scattering natural lens within the capsular bag and implantation of a new artificial lens can avoid blindness and give the patients clear vision again.

Femtosecond laser surgery of the human cornea has been introduced into clinics within last few years [3]. This technology uses the phenomena of photodisruption to create microbubbles within the cornea to separate the tissue. By scanning of this laser spot 3 dimensional cuts can be performed to create a flap for a later Excimer laser based LASIK procedure or also to cut to a precise lenticule to correct also the refraction of the eye e.g. with Visumax laser system (www.meditec.zeiss.com) [4].

Femtosecond laser cataract surgery has also been successfully introduced in the last few years. Here the main treatment is to open the capsular bag by a centered circular cut and to destroy the cataract lens by a crossed cut or by chopping the lens into tiny parts which can then be easily removed from the capsular bag with less ultrasonic power of the phacoemulsification device (www.lensxlasers.com).

Femtosecond laser surgery for the treatment of presbyopia [5] has also been proposed in the past and its main approach was to soften the natural human lens to regain elasticity and again increase the amplitude of accommodation. This softening can be done with help of cutting gliding planes or with a lot of microbubbles to become a sponge like structure. This model is mainly based on the Helmholtz model of accommodation where the stiffness of the lens material plays the most important role.

Presently available femtosecond laser technology

Femtosecond lasers became to be employed in creating flaps in the cornea during the refractive surgery and it soon became evident that one could make precisely shaped and adequately deep corneal pockets for future ports through which to pass the micro instruments and to create a well-defined and well centered circular, curvilinear capsulorhexis.

Further it became possible to create radial incisions in the material of the nucleus with adequate depth so as not to disturb the posterior capsule. For this purpose the posterior capsule was visualized pre operatively by means of OCT.

After making these incisions the patient is transferred to the operation room where the surgeon actually opens these ports and removes the remnants of the capsule, performs hydrodissection, cracks the fragments and aspirates each one them individually. Also the cortical matter is removed using standard I/A technique.

All the while a docking port is kept on the eye to be operated with a sterile contact lens with help of vacuum. This prevents the eye movements during the surgery.

The laser beam is centrally located and sourced from a distance far from the eye. The laser beam works on principle of Free space delivery system [6].

After the parameters and data are entered into the computer located in the console of the machine the eye is docked and laser beam is applied.

Drawbacks of the present solutions in ophthalmic femtosecond laser surgery [7].

Following is the list of contra-indications provided by the manufacturers and surgeons to use of femtosecond laser assisted cataract surgery in general:

1. Patients with glaucoma
2. Pediatric age group
3. Patients with corneal opacities
4. Patients with descemetocele
5. Hyphaema
6. Hypotony and/or in presence of corneal implants
7. In patients with poorly dilating pupils e.g. pseudoexfoliation
8. Severe basement membrane disease
9. Patients with zonular instability
10. Patients with keratoconus
11. Pregnant and lactating women
12. Thin cornea (thickness < 300 μm)
13. Severe dry eyes
14. Conditions of cornea precluding the transmission of laser light
15. Very high myopia
16. Stromal vascularisation
17. Reduced or absent sensation in cornea
18. Unhealthy epithelium.

In short, a very expensive device is created which can work only in “ideal” conditions. This is not appealing to many surgeons world-wide. Especially for those who work in developing countries or emerging economies.

What are we proposing?

What we propose here is to create anterior and posterior segment platforms using ultra short duration (femtosecond) laser energy for the treatment of anterior segment as well as posterior segment diseases. To best of our knowledge presently no femtosecond laser based surgical device exists which has capability of treating conditions of both segments.

We have selected a number of retinal conditions which could be successfully treated using femtosecond laser.

The available technology is not adequate to treat retinal conditions mainly because of free space delivery system. This beam cannot be controlled and regulated to a particular direction, intensity and energy because the numerical aperture is fixed.

Due to this major drawback the Fs-pulsed lasers are not used to treat the retinal conditions but proposals have been made to overcome the issue of reduced focus spot quality e.g. with help of adaptive optics (Lubatschowski US 2009048586) or more simply, accept needed higher pulse energy at reduces repetition rates to reduce thermal power to become acceptable. This group uses also OCT to adjust intra-ocular position of the treatment spots (Lubatschowski EP2410902) [8] in a free space delivery system.

In order to overcome these remaining pitfalls and shortcomings it becomes necessary to design a device and/or a system of devices which could be employed successfully to overcome not only the present contraindications of cataract surgery but also to enable surgical treatment of retinal conditions.

The solution

Our proposal is to create a handpiece suitable enough to deliver the femtosecond laser beam directly on ocular tissue which could be easily held in the hands by surgeon. Very much akin to the phacoemulsification handpiece. It will be held by surgeon like a pen and surgery will be performed much like usual cataract surgery.

As such it will comprise of three components:

1. Laser console
2. Flexible cable transmitting the Fs-laser beam
3. Handpiece.

The laser source

With regards to the laser source, an ultrashort duration pulse laser source in the wavelength range of 800 – 1100 nm, repetition rate of 1 kHz - 10 kHz, pulse width of 100 fs - 20 ps and pulse energy in range of 100 nJ - 100 μJ should be adequate enough. This should be to keep within thermal and acoustic confinement with regard to the minimal invasive tissue interaction needed in ophthalmology surgery.

Ytterbium (Yb) [9] fiber ultrashort pulse lasers very much fulfil these conditions.

In order to address smaller spot diameters and/or a better laser ablation because of higher linear absorption coefficients of ocular tissue, shorter wavelengths of the lasers mentioned are foreseen.

This can be achieved mainly with help of nonlinear optics (generation of higher harmonic radiation) like frequency doubling (SHG) tripling (THG) etc. to get 532 nm, 355 nm, 266 nm and 213 nm wavelengths with some other parameters of the laser.

A second pilot beam laser in the visible wavelength range is needed and co-aligned to the described surgical ultrashort pulsed laser beam to show the surgeon the cutting position of the invisible surgical laser beam.

Preferable is red pilot beam in wavelength range from 600 - 780 nm will be used and will have for it pilot beam function laser class 1 classification. It is foreseen to increase its power up to laser class 4 for use as additional coagulation laser to support the surgery with the surgical ultrashort pulse laser.

Flexible connecting cable

With regards to the flexible connecting cable which are capable of transmitting an ultrashort pulse laser beam we propose following two types of cables [10]. They are both capable of delivering ultrashort pulses at high repetition rates and energy levels up to a few milli joules (mJ) and 1030 nm wavelength damage free in a robust single mode fashion.

| 19 cell hypocycloid kagome HC-PCF | 7 cell hypocycloid kagome HC-PCF |
|---|---|
| Inner core diameter $\phi = 80 \mu\text{m}$ | Inner core diameter $\phi = 55 \mu\text{m}$ |
| Corresponding mode field diameter | Corresponding mode field diameter |
| (MFD) = $64 \mu\text{m}$ | (MFD) = $44 \mu\text{m}$ |
| Outer silica strut 780 nm | Outer silica strut 1300 nm |
| Curvature b optimized and close to 1 | Curvature b optimized and close to 1 |
| Numerical aperture NA = 0.012 | Numerical aperture NA = 0.018 |
| Group velocity dispersion (GVD) | Group velocity dispersion (GVD) |
| +0.8 ps/nm/km | -16 ps/nm/km |
| Measured loss = 200 dB/km | Measured loss = 45 dB/km |
| Staggering power overlap (PO) | Staggering power overlap (PO) |
| 2.8×10^{-6} | 4.7×10^{-5} |

Some authors have successfully delivered 1030 nm laser at 600fs and energy levels up to a few Petawatt/cm² in direct delivery focus free mode.

Handpiece

General considerations

An ophthalmic handpiece for focusing the laser beam to a spot diameter < 20 μm for the laser disruption mode and has a working distance of about < 2 mm from the target tissue will be the manually guided surgical instrument itself.

In an alternative laser ablation mode e.g. with highly absorbed wavelengths in ocular tissue like discussed 355 nm, 266 nm or 213 nm the spot diameter is less critical and will be <100 μm for the laser ablation mode.

This handpiece is supported by the laser source, the flexible connecting cable and the computer as main parts of the ophthalmic system solution provided.

The handpiece will have an irrigation system to keep the exit window clean and provide good focusing conditions for focusing in air onto the tissue surface as well as within the optical refractive index of the irrigation solution like physiologic salt solution or water.

Care will be taken to get a homogenous irrigation flow in front of the handpiece after the exit window to get also a homogenous refractive index profile to assure a good focus spot quality in the liquid.

If this condition isn't realised then focusing conditions will become very bad and a theoretical focus diameter of about 10 μm will be enlarged to about 100 μm which will need about 100 times more laser pulse energy to get photodisruption and the resulting surgical cut.

Hence it is in scope of this invention to provide besides a focusing handpiece for focusing in air and an irrigation system to clean the handpiece in between the laser emission.

In order to take care about a reproducible and smallest laser focus diameter and its quality the irrigation flow will be integrated around the central optical beam path to fulfil following tasks:

1. Cleaning the handpiece laser exit window.
2. Providing a reproducible and possibly homogenous flow of irrigation fluid.

The handpiece will be made of titanium to make it very light weight but at the same time to make it sturdy. The handpiece will be cylindrical in shape. The proximal end (the end from where the flexible cable will enter the handpiece) will have an extra port from there the irrigation solution will be infused. At the distal end there will be small projection for irrigation solution to come out.

The laser delivery cable will occupy complete space inside the cylinder and irrigation system will run co-axially right upto the tip.

Computer

The console has a miniature computer which has software for regulating:

- The output energy level.
- The brightness regulation of aiming beam.
- Counter for measuring number of laser applications for single shot and multiple shots.
- To interchange from continuous wave to pulsed delivery mode.

Application of the device

The femtosecond laser technology represents one of the latest links in the chain of evolution of ocular surgery in human beings. As always any invention is directed towards improving the health of humans and at the same time making the working conditions of the operating surgeon more tolerable by optimizing speed of the surgery with minimal stress to the tissue as well as surgeon.

As such retinal surgery is complicated and time consuming. Especially surgery for proliferative diabetic retinopathy where massive proliferative membranes invade the retinal surface. To free the surface of such membranes with minimal harm to underlying retina ensures good post-operative results.

As we know using metallic instruments for segmentation or delineation of the membranes e.g. by using segmentation scissors or vitrectomy cutter in itself is cause of secondary proliferation as the metallic ions serve to stimulate additional tissue reaction.

Precision cutting of tissue without using metallic instruments will play decisive role in conditions like subretinal neoplastic growths.

Following are the conditions we believe this invention will be of particular use

1. Segmentation of proliferative membranes in DPR.
2. Tractional retinal detachment with multiple fibrosis.
3. Performing high precision retinotomies for any pathology.
4. Subhyloid hemorrhagic clots.
5. Severe PVR.
6. Removal of choroidal tumors or other neoplastic growths.

Additionally this handpiece could be utilised for following purposes:

1. Photoablation of epiretinal membranes.
2. Drilling holes in sclera especially where predetermined hole diameter is calibrated (Antiglaucoma surgery).
3. Maybe the femtosecond laser delivered directly on cataract for its fragmentation controlled by surgeon thus overcoming the contraindications currently existing.

Conclusions

In conclusion it may be pointed out that several restrictions that can be seen on the present technology could be overcome and thereby employing ultrafast lasers in femtosecond range for treatment of ocular diseases e.g. diseases of lens, sclera, retina and subretinal choroidal tissue.

By being handy it will one day become a simpler device for the operating surgeons who will save time and stress. Which in turn will benefit their patients. The less operating time means less exposure to light thereby less chances of phototoxicity of macula. Visual rehabilitation will be early.

Any new technology is expensive to begin with in the early stages but once it becomes popular then the demand increases and prices decrease.

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